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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/297,981	05/10/99	MEHEUS L	INNS011/KAM

HM22/1206

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EXAMINER	
ZEMAN, R	
ART UNIT	**PAPER NUMBER**
1645	11

DATE MAILED: 12/06/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/297,981	Meheus et al.
Examiner	**Group Art Unit**
Robert A. Zeman	1645

☒ Responsive to communication(s) filed on *May 10, 1999*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-6, 14, 15, and 19-23* is/are pending in the application.

Of the above, claim(s) *4, 6, 14, and 15* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-3, 5, and 19-23* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-6, 14, 15, and 19-23* are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

Applicant's election of Invention I, **with traverse**, in Paper No. 9 is acknowledged. Applicant argues that the restriction requirement outlined in Paper No. 8 was improper since there was a unity of invention and the no undue burden would be imposed on the examiner in searching claims directed to linear, branched and circular peptides since a single search of the claimed sequences would cover all variants of said peptides. Said arguments have been fully considered and found not to be persuasive. Since the claimed special technical feature was known in the art at the time of the invention unity of invention does not exist (see Rawal et al. Biochimica et Biophysica Acta Vol. 1248 (1995) pages 11-18). Additionally, contrary to Applicant's assertion, searching of different peptide forms (linear, branched and circular) would require more than a single search of the claimed amino acid sequences. Consequently, claims 4, 6 and 14-15 are withdrawn from consideration. Claim 15 is withdrawn since it is dependent on a non elected invention (claim 14). Claims 1-3, 5 and 19-23 are pending and currently under examination.

Specification

The disclosure is objected to because of the following informalities: The description of Drawings is not labeled as such. The proposed amendment outlined in Paper No. 9 was not entered due to improper instructions. Amendments cannot be used to move text from one

location to another. The relevant material must be deleted and then presented as new text to be inserted at the appropriate location. Appropriate correction is required.

Claim Objections

Claims 1-3 and 5 are objected to because of the following informalities: each claim should be introduced by an article. Independent claims should be introduced by "A" or "An" and dependent claims by "The". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for peptides comprising the amino acid sequence of SEQ ID NO:1-15, does not reasonably provide enablement for "analogues of said peptides comprising conservative amino acid substitutions". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Applicant fails to define what is meant by an "analog". The specification is silent on what percentage of divergence is required to be considered an analog

and at what point does an "analog" become totally unrelated. Applicant fails to disclose what biochemical/immunological properties must be present in order for a peptide to be considered an "analog". Consequently, it would be impossible for one of skill in the art to ascertain what would fall under the category "analog".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5 and 19-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite by the use of the phrases "symmetrical dimethyl arginine" and "asymmetrical dimethyl arginine". A cursory search of the art revealed no indication of the meanings of said terms. Consequently, it is impossible to determine the metes and bounds of the claimed invention. Said claim is also indefinite because it recites material in parentheses. It is not clear whether said material is essential to the material being claimed. The use of commas instead of parentheses is suggested if the material is essential.

Regarding claim 19, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Additionally, use of the phrase "can be implicated" renders said claim vague and

indefinite. Is the associate of EBV with a disease state a limitation of the claimed invention? As written it is impossible to determine the metes and bounds of the claimed invention.

Claim 20 is rendered vague and indefinite by the use of the phrase "attached to specific locations." It is unclear whether said phrase refers to a type of arrangement on the substrate or a specific portion of said substrate. Additionally, it is unclear what is meant by a "range of peptides". It is unclear what peptides are to be included in the claimed kit. As written it is impossible to determine the metes and bounds of the claimed invention.

Claim 21 is rendered vague and indefinite by use of the phrase "in the form of parallel lines". It is unclear whether "parallel lines" refers to the arrangement of peptides on the membrane or the peptides themselves.

Claim 22 is rendered vague and indefinite by the use of the term "certain peptides". It is unclear which peptides are to be attached to the solid support and which are not. Consequently it is impossible to determine the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-2, 19-20 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Heipe et al. (U.S. Patent 5,945,105).

Said reference discloses peptides of 35 to 45 amino acids comprising SEQ ID NO:1 and SEQ ID NO:4 as well as kits containing said peptides bound to a solid support.(see column 4, lines 59-67 to column 6, lines 51).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5, 19-21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rokeach et al. (PNAS Vol. 85 pages 4832-4836) in view of Rawal et al. (Biochimica et Biophysica Acta Vol. 1248 (1995) pages 11-18, IDS-10).

Rokeach et al. disclose the sequence for the human Sm-D autoantigen as well as a peptide comprising SEQ ID NO:1 representing a fragment of the human Sm-D autoantigen (see page 4833) and that said autoantigen is associated with Lupus erythematosus. Rokeach et al also disclose other fragments of the Sm-D proteins. Finally, Rokeach et al. disclose that the "amino acid sequence reveals a (Gly-Arg) repeated motif at the C-terminus which may constitute on e of the Sm-D immunoreactive determinants" and that the C-terminus demonstrates a good homology to protamines and the Epstein-Barr nuclear antigen (see abstract). Rokeach et al. et al. differs from the instant invention in that the disclosed peptide sequences do not specifically recite N^G-monomethylargine, N^G, N^G-dimethylarginine or N^G, N'^G-dimethylarginine. Rawal et al. however, disclose that N^G-monomethylargine, N^G, N^G-dimethylarginine or N^G, N'^G-dimethylarginine residues are commonly observed in glycine-and-arginine rich motifs. Rawal et al. further disclose methods for generating and testing glycine-and-arginine rich peptides with various methylation patterns. Consequently it would have been obvious for one of skill in the art to apply the methodology disclosed by Rawal et al. to generate and test human Sm-D autoantigen peptides to generate Sm-D peptides that could be used in testing for Lupus erythematosus. One

would expect to be successful since it is known that the Sm-D is associated with the lupus disease state and that the glycine-arginine repeated motif at the C-terminus represents one of the Sm-D immunoreactive determinants.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can be reached between the hours of 7:30 am and 4:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner can be reached at (703) 308-1032 or the examiner's supervisor, Lynette Smith, can be reached at (703)308-3909.

DONNA WORTMAN
PRIMARY EXAMINER

Robert A. Zeman

December 4, 2000